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EXAMINER	
MCEVOY, THOMAS M	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,515	FUKUZAWA ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) *8 and 11-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,24,27 and 28* is/are rejected.

7)☒ Claim(s) *25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Schraga (US 2003/0050656).

Regarding claims 1 and 27, Schraga discloses a lancing device comprising: a first moving member 24 holding a lancing member 25 moved from a standby position (Figure 2) to a puncturing position (Figure 5; or any position distal of the standby position) in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 40 connected to the first moving member for controlling the movement of the first moving member; a housing 20 for accommodating the first and the second moving members while allowing the movement of the moving members; a movement converting mechanism (interaction of 28, 30 and 44) for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position (the second

moving member could be moved to a distal point just before member 47 is latched and then moved proximally to cause advancing movement of the first moving member); and an impact absorbing means that comes into stopping contact with the second moving member in the retreating movement for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation (member 46/47 must come into stopping contact with the housing wall or member 40 must come into stopping contact with the opening of the housing; Applicant's disclosure makes clear that the scope of an impact absorbing means can include portions of already claimed members like the tapered opening of the second moving member). Regarding claim 28, in the Figure 8 embodiment the second moving member 60 is latched to the housing (at 65) at the advanced position while being urged toward the retreated position (otherwise member 65 would not be needed); wherein when the second moving member is unlatched from the housing, the second moving member moves from the advanced position toward the retreated position for causing the lancing member to move toward the puncturing position together with the first moving member (the second moving member could be moved to a distal point just before member 64 is latched and then moved proximally to cause advancing movement of the first moving member).

3. Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent).

Regarding claims 1 and 27, Garthe et al. disclose a lancing device comprising: a first moving member, 40 or 51 or 40/51, holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target

portion by the lancing member; a second moving member 60 or 60/61 connected to the first moving member, for controlling the movement of the first moving member; a housing 11 for accommodating the first and the second moving members, while allowing the movement of the moving members; a movement converting mechanism 61/52/53 (a mechanism can comprise already claimed structural components; Examiner notes that Applicant's mechanism requires the grooves of the first and second moving members to function) for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position; and an impact absorbing means 53', connected to the housing, that comes into stopping contact with the second moving member in the retreating movement for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation.

4. Claims 1-4, 6, 7, 9, 24 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitson et al. (US 7,144,404 B2).

Regarding claims 1-3, 6 and 27, Whitson et al. disclose a lancing device comprising: a first moving member 22/24 holding a lancing member moved from a standby position (position 4, Figure 7) to a puncturing position (position 1, Figure 7; a position ready to initiate puncturing, etc.; the claim term is not well defined) in a puncturing direction (in moving from 4 to 1, the first moving member moves in a direction towards a final puncturing position) for puncturing a target portion by the lancing member; a second moving member 12 connected to the first moving member, for controlling the movement of the first moving member; a housing 240/242 for

accommodating the first and the second moving members while allowing the movement of the moving members; a movement convening mechanism for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position (evident from Figures 6 and 7; note horizontal line of cross-hairs in Figure 7 demarking a longitudinal position of the first moving member; note that second moving member is retreating from positions 3 to 4 to 1); and an elastically deforming impact absorbing means 28 that comes into stopping contact with the second moving member in the retreating movement (spring 28 is biased in puncturing direction so it must provide resistance to stop or assist in stopping member 12; Examiner notes that this recoil portion of the retreating movement in this application and the prior art does not result in opposite movement of the first moving member), connected to the housing (via member 90) for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation. Regarding claim 4, the housing is provided with a projection 90 for fixing the elastic member, the elastic member being a ring (series of rings) fitting around the projection. Regarding claim 7, member 90 can be considered as an operating portion and it connects to members 288/289 through an open end of the housing. Regarding claim 9, the movement converting mechanism comprises a link 16 connecting the first and second moving members and the second moving member 12 has grooves which allow the shaft of the link to rotate and therefore move. Regarding claim 24, reciprocal (up and down) movement of the second moving member (positions

1 to 2 to 3 to 4 to 1, Figure 7) is transformed into reciprocal movement of the first moving member (see comments for claim 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2, 3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent) in view of Alden et al. (US 7,033,371 B2) and Stanton (US 2,993,698).

Regarding claims 2 and 3, Garthe et al. fail to disclose an elastically deforming impact absorbing means as claimed. Alden et al. teach that mechanical stops in a lancet (such as the groove of Garthe et al.) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Stanton discloses that a vibration transferred to a link in a groove (similar to the link and groove of Garthe et al.) can be minimized by lining the groove with rubber (col. 3, lines 1-11 and elsewhere). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (groove sections) of the Garthe et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the groove to dampen the vibrations as taught by Stanton. Regarding claim 9, the movement converting mechanism comprises a link 61 connecting the first and the second moving members for moving the first moving member upon the movement of

the second moving member, wherein the first moving member is formed with a groove for allowing movement of a shaft of the link (Figures 4A-C). Regarding claim 10, the elastic member would be provided at upper and lower ends of the groove.

7. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitson et al. (US 7,144,404 B2) in view of Alden et al. (US 7,033,371 B2) and Tone (US 4,328,879).

Regarding claims 5 and 10, Whitson et al. disclose the device as described above but fail to disclose an elastic support in the groove. Alden et al. teach that mechanical stops in a lancet (such as the grooves of member 12 of Whitson et al.; especially at the impact points 1-4) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Tone teaches that it is known in a variety of arts to line a variety of gear drives with rubber in order to minimize shock and vibration (col. 1, lines 14-29). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (grooves and corners of member 12) of the Whitson et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the parallelogram of member 12 or around gear 16 to dampen the vibrations as taught by Tone.

Response to Arguments

8. Applicant's arguments filed September 15th 2010 regarding the previous 35 U.S.C. 112 1st rejection of record have been fully considered and are persuasive. Therefore the rejection has been withdrawn. The remainder of Applicant's arguments are not persuasive. Applicant has argued on page 2 of the response that Schraga does

not disclose equivalent means as required by the means plus function language of claim 27. Nowhere in Applicant's specification is any group of parts identified as the movement converting means. Like Applicant, Schraga discloses a movement converting mechanism with two movable members - one associated with the trigger, the other holding a lancet - movable relative to eachother as claimed, where the two movable members do not appear fundamentally different than Applicants. They are connected by a gear movable around a pin rather than a series of levers movable around a pin. This appears to be an equivalent means. Applicant is respectfully requested to identify on record what they would consider as equivalent means. Applicant has argued on pages 3 and 4 of the response that Schraga fails to disclose an impact absorbing means. Member 40 of Schraga can come into stopping contact with the housing when operated in the manner as described above. Applicant's impact absorbing means is essentially part of the housing in several embodiments. Examiner has not proposed operating the device of Schraga exactly as depicted in Schraga which Applicant appears to be basing the argument on. Applicant has argued on pages 5 and 6 that the mass 60 of Garthe et al. does not cause movement of member 40 by adding to the rotational force of member 51. Even if this interpretation is not found persuasive, Examiner considers it fully disclosed in Garthe et al. that the timing of the impulse force (a force in the puncturing direction) can be engineered to occur at any point between -1000 to +1000 milliseconds around impact (paragraph 0016). Therefore, some situations are disclosed where an impulse force (caused by retreating movement of member 60 – paragraph 0031) would occur that drives the lancing member, via

movement of the housing, to a puncturing position due to the impulse occurring as the lancing member is moving forward already or as it is at the apex of its puncturing movement. Applicant's arguments regarding Whitson et al. have already been addressed in the previous office action of record. However, it is worth restating that Examiner is relying on the movement from position 4 to 1, not 1 to 2, where a "puncturing position" is not well defined by the claims.

Allowable Subject Matter

9. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/(Jackie) Tan-Uyen T. Ho/
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